6 Software Engineering for Health Care and Biomedicine

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After reading this chapter, you should know the answers to these questions:

- What key functions do software applications perform in health care?
- How are the components of the software development life cycle applied to health care?
- What are the trade-offs between purchasing commercial, off-the-shelf systems and developing custom applications?
- What are important considerations in comparing commercial software products?
- Why do systems in health care, both internally-developed and commercially-purchased, require continued software development?

6.1 How Can a Computer System Help in Health Care?

Chapter 5 discusses basic concepts related to computer and communications hardware and software. In this chapter, we focus on the software applications and components of health care information systems, and describe how they are used and applied to support health care delivery. We give examples of some basic functions that may be performed by health information systems, and discuss important considerations in how the software may be acquired, implemented and used. This understanding of how a system gets put to use in health care settings will help as you read about the various specific applications in the chapters that follow.

Health care is an information-intensive field. Clinicians are constantly collecting, gathering, reviewing, analyzing and communicating information from many sources to make decisions. Humans are complex, and individuals have many different characteristics that are relevant to health care and that need to be considered in decision-making. Health care is complex, with a huge body of existing knowledge that is expanding at ever-increasing rates. Health care information software is intended to facilitate the use of this information at various points in the delivery process. Software defines how data are obtained, organized and processed to yield information. Software, in terms of design, development, acquisition, configuration and maintenance, is therefore a major component of the field. Here we

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provide an introduction to the practical considerations regarding health information software. This includes both understanding of general software engineering principles, and then specifically how these principles are applied to health care settings.

To this aim, we first describe the major software functions within a health care environment or health information system. While not all functions can be covered in detail, some specific examples are given to indicate the breadth of software applications as well as to provide an understanding of their relevance. We also describe the software development life cycle, with specific applications to health care. We then describe important considerations and strategies for acquiring and implementing software in health care settings. Finally, we discuss emerging software engineering influences and issues and their impact on health information systems. Each system can be considered in regard to what it would take to make it functional in a health care system, and what advantages and disadvantage the software may have, based on how it was created and implemented. Understanding this will help you identify the risks and benefits of various applications, so that you can identify how to optimize the positive impact of health information systems.

6.2 Software Functions in Health Care

6.2.1 Cases Study of Health Care Software

The following case study illustrates many important functions of health care software.

James Johnson is a 42-year old man living in a medium-sized western U.S. city. He is married and has two children. He has Type-II diabetes, but it is currently well-controlled and he has no other health concerns. There is some history of cardiovascular disease in his family. James has a primary care physician, Linda Stark, who practices at a clinic that is part of a larger health delivery network, Generation Healthcare System (GHS). GHS includes a physician group, primary and specialty care clinics, a tertiary care hospital and an affiliated health insurance plan.

James needs to make an appointment with Dr. Stark. He logs into the GHS **patient portal** *and uses an online scheduling application to request an appointment. While in the patient portal, James also reviews results from his most recent visit and prints a copy of his current medication list in order to discuss the addition of an over-the-counter supplement he recently started taking.*

Before James arrives for his visit, the clinic's scheduling system has already alerted the staff of James's appointment and the need to collect information related to his diabetes. Upon his arrival, Dr. Stark's nurse gathers the requested diabetes information and other vital signs data and enters these into the **electronic health record** *(EHR). In the exam room, Dr. Stark reviews James's history, the new information gathered today, and recommendations and reminders provided by the EHR on a report tailored to her patient's medical history. They both go over James's medication list and Dr. Stark notes that, according to the EHR's drug interaction tool, the supplement he is taking may have an interaction with one of his diabetes medications. One of the reminders suggests that James is due for an HbA1c test and Dr. Stark orders this in the EHR. Dr. Stark's nurse, who has been alerted to the lab test order, draws a blood sample from James. Before the appointment ends, Dr. Stark completes and signs his progress note and forwards a visit summary for James to review on the patient portal.*

A few days after his appointment, James receives an email from GHS that alerts him to an important piece of new information in *his patient record. Logging into the patient portal application, James sees that his HbA1c test is back. The test indicates that the result is elevated. Dr. Stark has added a note to the result saying that she has reviewed the lab and would like to refer James to the GHS Diabetes Specialty Clinic for additional follow-up. James uses the messaging feature in the patient portal to respond to Dr. Stark and arrange for an appointment. James also clicks on an* **infobutton** *next to the lab result to obtain more information about the abnormal value. He is linked to patient-focused material about HbA1c testing, common causes for high results, and common ways this might be addressed. Lastly, James reviews the visit summary note from his appointment with Dr. Stark to remind him about suggestions she had for replacing his supplement.*

At his appointment with the Diabetes Specialty Clinic, James notes that they have access to all the information in his record. A diabetes care manager reviews the important aspects of James's medical history. She suggests more frequent monitoring of his laboratory test results to see if he is able to control his diabetes without changes to his medications. She highlights diet and exercise suggestions in his patient portal record that have been shown to help. The care manager sends a summary of the visit to Dr. Stark so that Dr. Stark knows that James did follow-up with the Clinic.

A year later, James is experiencing greater difficulty controlling his diabetes. Dr. Stark and the Diabetes Care Manager have continued to actively monitor his HbA1c and other laboratory test results, and occasionally make changes to his treatment regimen. They are able to use the EHR to track and graph laboratory test results and correlate them with changes in medications. Due to family problems, James struggles with adherence to his medication regimen, and he is not maintaining a healthy diet. As a result, his blood sugar has become seriously unstable and he is taken to the GHS hospital emergency department. Doctors in the ED are able to access his electronic record through a Web-based interface to the clinic EHR. His medication and lab history, as well as notes from Dr. Stark and the care manager, help them quickly assess his condition and develop a plan. James is admitted as an inpatient for overnight observation and, again, doctors and nurses on the ward are able to access his full record and record new observations and treatments, which are automatically shared with the outpatient EHR. They are also able to reconcile his outpatient prescriptions with his inpatient medications to ensure continuity. James is stabilized by the next day. He receives new discharge medications, which simultaneously discontinue his existing orders.

Because Dr. Stark is listed as James's primary care physician, she is notified both at admission and discharge of his current status. She is able to review his discharge summary in the EHR. She instructs her staff to send a message through the patient portal to James to let him know she had reviewed his inpatient record and to schedule a follow-up appointment.

The GMS EHR is also part of a statewide **health information exchange** *(HIE), which allows medical records to be easily shared with health care providers outside a patient's primary care provider. This means that if James should need to visit a hospital, emergency department or specialty care clinic outside the GMS network, his record would be available for review and any information entered by these outside providers would be available to Dr. Stark and the rest of the GMS network. In James's state, the local and state health departments are also linked to the HIE. This allows clinics, hospitals and labs to electronically submit information to the health departments for disease surveillance and case reporting purposes.*

Back at home, James's wife, Gina, is able to view his record on the GHS patient portal because he has granted her proxy access to his account. This allows her to see the note from Dr. Stark and schedule the follow-up appointment. Gina also views the discharge *instructions that were electronically sent to James's patient record. As she looks deeper into information about diabetes that GHS had automatically linked to James's record, Gina sees a note about a research study into genetic links with diabetes. Concerned about their two children, Gina discusses the study with James, and he reviews the on-line material about the study. Growing interested in the possible benefits of the research, James enrolls electronically in the study and is later contacted by a study coordinator. Because GHS researchers are conducting the study, relevant parts of James's EHR can be easily shared with the research data tracking system.*

This fictional case study highlights many of the current goals for improving health care delivery, including: improved access to care, increased patient engagement, shared patient-provider decision-making, better care management, medication reconciliation, improved transitions of care, and research recruitment. In the case study, each of these goals required software to make health information accessible to the correct individuals at the proper time.

In today's health care system, few individuals enjoy the interaction with software depicted in the case study with James Johnson. Although the functions described in the scenario exist at varying levels of maturity, most health care delivery institutions have not connected all the functions together as described. The current role of software engineering in health care is therefore twofold: to design and implement software applications that provide required functions, and to connect these functions in a seamless experience for both the clinicians and the patients.

The case study also highlights the usefulness of several functions provided by health care software applications for clinicians, patients, and administrators. Some of these functions include:

1. Acquiring and storing data
2. Summarizing and displaying data
3. Facilitating communication and information exchange
4. Generating alerts, reminders, and other forms of decision support
5. Supporting educational, research, and public health initiatives

6.2.2 Acquiring and Storing Data

The amount of data needed to describe the state of even a single person is huge. Health professionals require assistance with data acquisition to deal with the data that must be collected and processed. One of the first uses of computers in a medical setting was the automatic analysis of specimens of blood and other body fluids by instruments that measure chemical concentrations or that count cells and organisms. These systems generated printed or electronic results to health care workers and identified values that were outside normal limits. Computer-based patient monitoring that collected physiological data directly from patients were another early application of computing technology (see Chap. 19). These systems provided frequent, consistent collection of vital signs, electrocardiograms (ECGs), and other indicators of patient status. More recently, researchers have developed medical imaging applications as described in Chaps. 9 and 20, including computed tomography (CT), magnetic resonance imaging (MRI), and digital subtraction angiography. The calculations for these computationally intensive applications cannot be performed manually; computers are required to collect and manipulate millions of individual observations.

Early computer-based medical instruments and measurement devices provided results only to human beings. Today, most instruments can transmit data directly into the EHR, although the interfaces are still awkward and poorly standardized (see Chaps. 4 and 7). Computer-based systems that acquire information, such as one's health history, from patients are also data-acquisition systems; they free health professionals from the need to collect and enter routine demographic and history information.

Various departments within a hospital use computer systems to store clinical data. For instance, clinical laboratories use information systems to keep track of orders and specimens and to report test results; most pharmacy and radiology departments use computers to perform analogous functions. Their systems may connect to outside services (e.g., pharmacy systems are typically connected to one or more drug distributors so that ordering and delivery are rapid and local inventories can be kept small). By automating processing in areas such as these, health care facilities are able to speed up services, reduce direct labor costs, and minimize the number of errors.

6.2.3 Summarizing and Displaying Data

Computers are well suited to performing tedious and repetitive data-processing tasks, such as collecting and tabulating data, combining related data, and formatting and producing reports. They are particularly useful for processing large volumes of data.

Raw data as acquired by computer systems are detailed and voluminous. Data analysis systems must aid decision makers by reducing and presenting the intrinsic information in a clear and understandable form. Presentations should use graphs to facilitate trend analysis and compute secondary parameters (means, standard deviations, rates of change, etc.) to help spot abnormalities. Clinical research systems have modules for performing powerful statistical analyses over large sets of patient data. The researcher, however, should have insight into the methods being used. For clinicians, graphical displays are useful for interpreting data and identifying trends.

Fast retrieval of information is essential to all computer systems. Data must be well organized and indexed so that information recorded in an EHR system can be easily retrieved. Here the variety of users must be considered. Getting cogent recent information about a patient entering the office differs from the needs that a researcher will have in accessing the same data. The query interfaces provided by EHRs and clinical research systems assist researchers in retrieving pertinent records from the huge volume of patient information. As discussed in Chap. 21, bibliographic retrieval systems are an essential component of health information services.

6.2.4 Facilitating Communication and Information Exchange

In hospitals and other large-scale health care institutions, myriad data are collected by multiple health professionals who work in a variety of settings; each patient receives care from a host of providers—nurses, physicians, technicians, pharmacists, and so on. Communication among the members of the team is essential for effective health care delivery. Data must be available to decision makers when and where they are needed, independent of when and where they were obtained. Computers help by storing, transmitting, sharing, and displaying those data. As described in Chaps. 2 and 12, the patient record is the primary vehicle for communication of clinical information. The limitation of the traditional paper-based patient record is the concentration of information in a single location, which prohibits simultaneous entry and access by multiple people. Hospital information systems (HISs; see Chap. 13) and EHR systems (Chap. 12) allow distribution of many activities, such as admission, appointment, and resource scheduling; review of laboratory test results; and inspection of patient records to the appropriate sites.

Information necessary for specific decision-making tasks is rarely available within a single computer system. Clinical systems are installed and updated when needed, available, and affordable. Furthermore, in many institutions, inpatient, outpatient, and financial activities are supported by separate organizational units.

Patient treatment decisions require inpatient and outpatient information. Hospital administrators must integrate clinical and financial information to analyze costs and to evaluate the efficiency of health care delivery. Similarly, clinicians may need to review data collected at other health care institutions, or they may wish to consult published biomedical information. Communication networks that permit sharing of information among independent computers and geographically distributed sites are now widely available. Actual integration of the information they contain requires additional software, adherence to standards, and operational staff to keep it all working as technology and systems evolve.

6.2.5 Generating Alerts, Reminders, and Other Forms of Decision Support

In the end, all the functions of storing, displaying and transmitting data support decision making by health professionals, patients, and their caregivers. The distinction between decision-support systems and systems that monitor events and issue alerts is not clear-cut; the two differ primarily in the degree to which they interpret data and recommend patient-specific action. Perhaps the best-known examples of decision-support systems are the clinical consultation systems or event-monitoring systems that use population statistics or encode expert knowledge to assist physicians in diagnosis and treatment planning (see Chap. 22). Similarly, some nursing information systems help nurses to evaluate the needs of individual patients and thus assist their users in allocating nursing resources. Chapter 22 discusses systems that use algorithmic, statistical, or artificial-intelligence (AI) techniques to provide advice about patient care.

Timely reactions to data are crucial for quality in health care, especially when a patient has unexpected problems. Data overload, created by the ubiquity of information technology, is as detrimental to good decision making as is data insufficiency. Data indicating a need for action may be available but are easily overlooked by overloaded health professionals. Surveillance and monitoring systems can help people cope with all the data relevant to patient management by calling attention to significant events or situations, for example, by reminding doctors of the need to order screening tests and other preventive measures (see Chaps. 12 and 22) or by warning them when a dangerous event or constellation of events has occurred.

Laboratory systems routinely identify and flag abnormal test results. Similarly, when patient-monitoring systems in intensive care units detect abnormalities in patient status, they sound alarms to alert nurses and physicians to potentially dangerous changes. A pharmacy system that maintains computer-based drug-profile records for patients can screen incoming drug orders and warn physicians who order a drug that interacts with another drug that the patient is receiving or a drug to which the patient has a known allergy or sensitivity. By correlating data from multiple sources, an integrated clinical information system can monitor for complex events, such as interactions among patient diagnosis, drug regimen, and physiological status (indicated by laboratory test results). For instance, a change in cholesterol level can be due to prednisone given to an arthritic patient and may not indicate a dietary problem.

6.2.6 Supporting Educational, Research, and Public Health Initiatives

Rapid growth in biomedical knowledge and in the complexity of therapy management has produced an environment in which students cannot learn all they need to know during training—they must learn how to learn and must make a lifelong educational commitment. Today, physicians and nurses have available a broad selection of computer programs designed to help them to acquire and maintain the knowledge and skills they need to care for their patients. The simplest programs are of the drill-and-practice variety; more sophisticated programs can help students to learn complex problem-solving skills, such as diagnosis and therapy management (see Chap. 21). Computer-aided instruction provides a valuable means by which health professionals can gain experience and learn from mistakes without endangering actual patients. Clinical decision-support systems and other systems that can explain their recommendations also perform an educational function. In the context of real patient cases, they can suggest actions and explain the reasons for those actions.

Surveillance also extends beyond the health care setting. Appearances of new infectious diseases, unexpected reactions to new medications, and environmental effects should be monitored. Thus the issue of data integration has a national or global scope (see the discussion of the National Health Information Infrastructure in Chaps. 1 and 16 that deals with public health informatics).

6.3 Software Development and Engineering

Clearly, software can be used in many different ways to manage and manipulate health information to facilitate health care delivery. However, just using a computer or a software program does not improve care. If critical information is unavailable, or if processes are not organized to operate smoothly, a computer program will only expose challenges and waste time of clinical staff that could be better applied in delivering care. To be useful, software must be developed with an understanding of its role in the care setting, be geared to the specific functions that are required, and it must be developed correctly. To be used, software must be integrated to support the users' workflow. We will discuss both aspects of software engineering – development and integration.

6.3.1 Software Development

Software development can be a complex, resource-intensive undertaking, particularly in environments like health care where safety and security provide added risk. The **software development life cycle** (SDLC) is a framework imposed over software development in order to better ensure a repeatable, predictable process that controls cost and improves quality of the software product (usually an application). SDLC is a subset of the systems development life cycle, focusing on the software component of a larger system. In practice, and particularly in heath care, software development encompasses more than just the software, often stretching into areas such as process re-engineering in order to maximize the benefits of the software product. Although SDLC most literally applies to an in-house development project, all or most of the life cycle framework is also relevant to shared development and even purchase of commercial off-the-shelf (COTS) software. The following is an overview of the phases of the SDLC.

6.3.1.1 Planning/Analysis

The software development life cycle begins with the formation of a project goal during the planning phase. This goal typically derives from an organization's or department's mission/vision, focusing on a particularly need or outcome. This is sometimes called project conceptualization. Planning includes some initial scoping of the project as well as resource identification (including funding). It is important that the project's scope also addresses what is not in the project in order to create appropriate expectations for the final product. A detailed analysis of current processes and needs of the target users is often done. As part of the analysis, specific user requirements are gathered. Depending on the development process, this might include either detailed instructions on specific functions and operating parameters or more general user stories that explain in simple narrative the needs, expected workflow and outcomes for the software. It is important that real users of the system are consulted, as well as those in the organization who will implement and maintain the software. The decision of whether to develop the software in-house, partner with a developer, or purchase a vendor system will likely determine the level of detail needed in the requirements. Vendors will want very specific requirements that allow them to properly scope and price their work. The requirements document will usually become part of a contract with a vendor and will be used to determine if the final product meets the agreed specification for the software. In-house development can have less detailed requirements, as the contract to build the software is with the organization itself, and can allow some evolution of the requirements as the project progresses. However, the more flexibility that is allowed and the longer changes or enhancements are permitted, the higher the likelihood of "scope creep" and schedule and cost overruns.

Other tasks performed during analysis include an examination of existing products and potential alternative solutions, and, particularly for large projects, a cost/benefit analysis. A significant and frequently overlooked aspect of the planning and analysis phase is to determine outcome measures that can be used during the life cycle to demonstrate progress and success or failure of the project. These measures can be refined and details added as the project progresses. The planning and analysis phase typically ends when a decision to proceed is made, along with at least a rough plan of how to implement the next steps in the SDLC. If the organization decides to purchase a solution, a request for proposals (RFP) that contains the requirements document is released to the vendor community.

The planning and analysis stage of software development is perhaps both the most difficult and the most important stage in the development lifecycle as it is applied to health care. Requirements for software in health care are inherently difficult to define for many reasons. Health care practice is constantly changing, and as new therapies or approaches are discovered and validated, these new advancements can change how care is practiced. In addition, the end users of health care software are comparatively advanced relative to other industries. Unlike industries where front-line workers may be directed by supervisors with more advanced training and greater flexibility in decision making, in health care the front-line workers are often physicians, who are the most advance-trained workers in the system (although not necessarily the most advanced with respect to computer literacy) and require the greatest flexibility for decisions. This flexibility makes it difficult to define workflows or even get indications of the workflows being followed, since physicians will not always make explicit what actions or plans are being pursued. This flexibility is important for patient care, because it allows front-line clinicians to adapt appropriately to different settings, staffing levels, and specialties. The need for flexibility is such that defining requirements for software that could reduce flexibility is criticized as "cookbook" medicine, and a common reason for resistance to software adoption. However, this resistance is not just characteristic of software – clinical guidelines and other approaches to structured or formalized care processes are also criticized, and the challenge of applying discovered knowledge to clinical care processes remains difficult.

Over time, however, there have been some successful efforts that have defined standard requirements for health information software. Among the most notable efforts have been in the EHRs, where groups have created lists of requirements and certified systems that match those requirements. The Certification Commission for Health Information Technology (CCHIT) began in 2004 and has emerged as perhaps the most notable of these efforts. CCHIT defines criteria for electronic health records' functionality, interoperability and security (Leavitt and Gallagher 2006). In addition, because CCHIT released criteria in different stages, it gave a preliminary prioritization of EHR functions. Later, the certification approach was adopted by the Office of the National Coordinator of Health Information Technology (ONC) in 2010, when they created a list of EHR functions that were most related to "meaningful use" of EHRs (Blumenthal and Tavenner 2010). These efforts have been significant in creating a consistent set of functions that have been subsequently incorporated into software products (Mostashari 2011).

6.3.1.2 Design

During the Design phase, potential software solutions are explored. System architectures are examined for their abilities to meet the needs stated in the requirements. Data storage and interface technologies are researched for appropriate fit. User front-end solutions are investigated to assess capabilities for required user input and data display functions. Other details, such as security, performance, internationalization, etc., are also addressed during design. Analysts with domain knowledge in the target environment are often employed during this phase in order to translate user requirements into suitable proposals. Simple mock-ups of the proposed system may be developed, particularly for user-facing components, in order to validate the design and identify potential problems and missing information. Closely related to this, an integrated, automated testing architecture, with appropriate testing scripts/procedures, may be designed in this phase in order to ensure the software being developed is both high quality and responsive to the requirements. The depth and completeness of the design is contingent on the software development process, as well as other factors. In some cases, the entire design is completed before moving on to software coding. In other development strategies, a high-level system architecture is designed but the details of the software components are delayed until each component or component feature is being programmed. The pros and cons of these approaches are discussed later in this chapter. For vendor-developed systems, the purchasing organization will often hold design reviews and demonstrations of mock-ups or prototypes with the vendor to assess the solutions. In the case of pre-built COTS software, the purchasing organization relies on the vendor's system description and reviews from third parties, supplemented by system demonstrations, to determine the appropriateness of the design. As with the Analysis phase, it is important to include the target users and IT operations personnel in the design reviews.

Ideally, the software could be designed solely around the care requirements and the use of information. However, rarely are the clinical requirements of the use case the only consideration. In the design phase, other requirements are considered, such as the software cost and how it integrates with an existing health IT strategy of an organization. Resources applied to a development project are not available for other potential projects, so costs are always influential. The design phase must consider various alternatives to meet the most important requirements, recognizing trade-offs and contingency approaches. Additional considerations are how the software will support long-term factors, not just the immediate requirements that have been identified. Clinicians and clinical workflow analysts are often the primary participants in the requirements analysis stage, whereas informaticians are more prominent in the design phase. This is because during this latter phase the clinical goals and strategies are considered together with what can be vastly different design approaches, and the ability to consider the various strengths and weaknesses of these different approaches is critical. Often, design considerations are between custom development, purchasing niche applications, or purchasing components of a monolithic EHR. The considerations of development versus COTS software is discussed in more detail in the Acquisition Strategy Sect. 6.3.3.1 below.

6.3.1.3 Development

Coding of the software is done during the Development phase of the SDLC. The software engineers use the requirements and system designs as they program the code. Analysts help resolve questions about requirements and designs for the programmers when it is unclear how software might address a particular feature. The software process defines the pace and granularity of the development. In some cases, an entire software component or system is developed at once by the team. In other cases, the software is broken down into logical pieces and the programmers only work on the features that are relevant to the piece they are currently working on. As software components are completed, unit tests are run to confirm the component is free of known bugs and produces expected outputs or results.

In health care, development includes coding of custom software as well as configuration of COTS software. Health care practices across institutions (and even within larger organizations) are so variable that all software requires some level –often substantial – of configuration. Configuration can range from assigning local values to generic variables within the software, to complete development of documentation templates, reports, and terminology. In fact, configuration can be so considerable that institutions name the software separately as their own configuration, with all the content that the users interact with being defined locally. This configuration is often done using tools built specifically for the commercial software, which facilitate the integration of the configuration products into the software infrastructure. The tools can be complex, requiring significant training for developers. Typically, tools work well for basic configuration and may also have advanced functionality that can configure more complicated templates or reports. The most intensive time investment for configuration is typically when the tools do not directly support certain configurations, and developers must find approaches to creatively adapt the development "around the tools."

6.3.1.4 Integration and Test

For complex software projects consisting of several components and/or interfaces with outside systems, an Integration phase in the SDLC is employed to tie together the various pieces. Some aspects of the integration software are likely done during the Development phase by simulating or mocking the outputs to, and inputs from, other systems. During Integration, these connections are finalized. Simulations are run to demonstrate functional integration of the various system components. Once the various components are integrated, a thorough testing regimen is conducted in order to prove the end-to-end operation of the entire software system. Specific test scenarios are run with known inputs and expected outputs. This is typically done in a safe, non-operational environment in order to avoid conflicts or issues with real-world people (e.g., patients and clinicians) and environments, although some inbound information from live systems may be used to verify scenarios that are difficult to simulate.

Testing and integration in health care are similar to other complex environments, in that it can be difficult to create a testing environment that matches the dynamics of the real-world setting. Generally, testing is done around multiple use cases or case studies, using data to support the cases. In the real world, however, there may be data and information that don't match the case studies, since both people and health care are complex. As a result, internally-developed applications are often provisionally used in a "pilot" phase as part of testing. For COTS software, companies may use simulation laboratories that try to mimic the clinical environment, or work with specific health care organizations as development and testing partners. Later, however, this can lead to challenges if data representing the dynamics of one organization are not easily transferrable, and software must be further tested with new environments. Issues with software transferability between institutions have been demonstrated in studies, even for specific applications (Hripcsak et al. 1998). Another challenge is that with current privacy laws, organizations are more reluctant to release data to vendors for testing.

6.3.1.5 Implementation

Once the software passes integration testing it moves to the implementation phase. In this phase, the software is installed in the live environment. In preparation for installation, server hardware, user devices, network infrastructure, facilities changes, etc., may need to be implemented and tested, too. In addition, user training will be performed in the weeks before the software goes live. Any changes to policies and procedures required by the software will also be implemented in the build-up to installation.

Health care presents interesting considerations in each phase of the software development cycle, but the challenges have been more visible in implementation than any other phase. This may be because health IT, while intended to facilitate more efficient workflows with information, is still disruptive. Disruption happens most during implementation, when clinicians actually begin using the software, and studies have shown that during this time clinical productivity does decline (Shekelle et al. 2006). If users do not perceive that the benefits are sufficient to justify this disruption, or if the efficiency does not improve quickly enough after the initial implementation, they may choose to disregard the software or even revolt against its implementation. There have been prominent examples in biomedical informatics of software implementations failing during implementation (Bates 2006; Smelcer et al. 2009), and even studies demonstrating harm (Han et al. 2005). Because of these risks, health IT professionals need to be flexible in implementation, and adapt the implementation strategies to how the system is adopted. Users have been shown to use health IT software in different ways for different benefits, and may need incentives or prodding to advance to different levels of use.

6.3.1.6 Verification and Validation

To ensure that the software satisfies the original requirements for the system and meets the need of the organization, a formal verification and validation of the software is performed. The implementing organization will *verify* that the software has the features and performs all the functions specified in the requirements document. The software is also *validated* to show that it performs according to specified operational requirements, that it produces valid outputs, and that it can be operated in a safe manner. For purchased software, the verification and validation phase is used by the purchasing organization in order to officially accept the software.

Since clinicians often use software at different levels or in different ways, tracking patterns of use can be an important approach for verification and validation of software in health care. Additionally, because they have experience working in complicated environments, users can be good at identifying inconsistencies in data or software functions. Two approaches that have been used and can be successful for validation are monitoring use, and facilitating user feedback.

6.3.1.7 Operations and Maintenance

Software eventually enters an operations and maintenance (O&M) phase where it is being regularly used to support the operational needs of the organization. During this phase, an O&M team will ensure that the software is operating as desired and will be fielding the support needs of the users. Updates may need to be installed as new versions of the software are released. This may require new integration and testing, implementation, and verification and validation steps. Ongoing training will be required for new users and system updates. The O&M team may conduct regular security reviews of the system and its use. Data repositories and software interfaces will be monitored for proper operation and continued information validity. Software bugs and feature enhancement requests will be collected. These may drive an entire new development life cycle as new requirements persuade an organization to explore significant upgrades to its current software or even an entirely new system.

Maintenance is a demanding task in health information software. It involves correcting errors; adapting configurations and software to growth, new standards, and new regulations; and linking to other information sources. Maintenance tasks can exceed by more than double the initial acquisition costs, making it a substantial consideration that should affect software design. COTS suppliers often provide maintenance services for 15–30 % of the purchase price annually, but custom development or configuration maintenance must be supported by the purchasing organization. If the software is not maintained, it can quickly become unusable in a health care setting.

6.3.1.8 Evaluation

An important enhancement to the SDLC suggested by Thompson et al. (1999) is the inclusion of an evaluation process during each of the phases of the life cycle. The evaluation is influenced by risk factors that may affect a particular SDLC segment. An organization might perform formative evaluations during each phase, depending on specific needs, in order to assess the inputs, processes and resources employed during development. During Verification and Validation or O&M, a summative evaluation may be performed to assess the outcome effects, organizational impact, and cost-benefit of the software solution.

Health IT is considered an intervention into the health care delivery system, so evaluations have been done and published as comparative studies in clinical literature (Bates et al. 1998; Evans et al. 1998; Hunt et al. 1998). These evaluations and syntheses of multiple studies have identified areas of impact and areas where the effect of health IT software is inconsistent. Researchers have also noted that most of these studies have occurred in institutions where software was developed internally, with disproportionate under-representation of COTS software systems in evaluations, especially considering that most health care institutions use COTS rather than internal development (Chaudhry et al. 2006). It is hoped that the existing evaluations can be a model for software evaluations of COTS, to clarify their impact on care.

6.3.2 Software Development Models

Different software development processes or methods can be used in an SDLC. The **software development process** describes the day-to-day methodology followed by the development team, while the life cycle describes a higher-level view that encompasses aspects that take place well before code is ever written and after an application is in use. The following are two of the most common examples of different development processes in clinical information systems development.

6.3.2.1 Waterfall Model

The Waterfall model of software development suggests that each step in the process happens sequentially, as shown in Fig. 6.1. The term "Waterfall" refers to the analogy of water cascading downward in stages. A central concept of the Waterfall methodology is to solidify all of the requirements, establish complete functional specifications, and create the final software design prior to performing programming tasks. This concept is referred to as "Big Design Up Front," and reflects the thinking that time spent early-on making sure requirements and design are correct saves considerable time and effort later. Steve McConnell, an expert in software development, estimated that "… a requirements defect that is left undetected until construction or maintenance will cost 50–200 times as much to fix as it would have cost to fix at requirements time" (McConnell 1996).

The waterfall model provides a structured, linear approach that is easy to understand. Application of the model is best suited to software projects with stable requirements that can be completely designed in advance. In practice, it may not be possible to create a complete design for software a priori. Requirements and design specifications can change even late in the development process. Clients may not know exactly what requirements they need before reviewing a working prototype. In other cases, software developers may identify problems during the implementation that necessitate reworking the design or modifying the requirements.

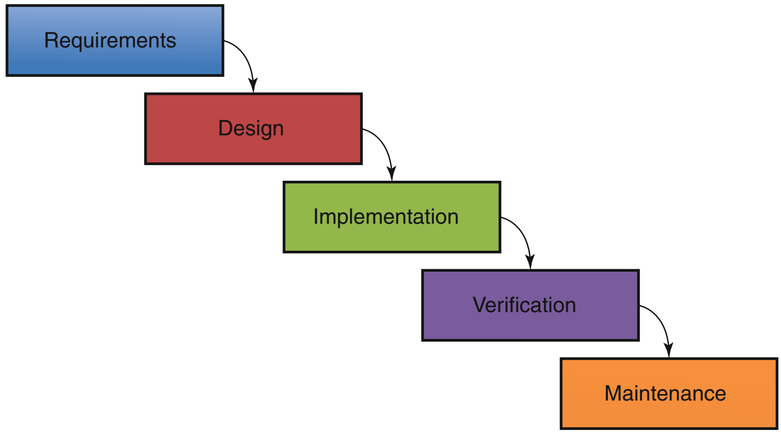
6.3.2.2 Agile Models

In contrast to the Waterfall model, modern software development approaches have attempted to provide more flexibility, particularly in terms of involving the customer throughout the process. In 2001, a group of software developers published the Manifesto for Agile Software Development, which emphasizes iterative, incremental development and welcomes changes to software requirements even late in the development process (Beck et al. 2001).

Agile development eschews long-term planning in favor of short iterations that usually last from 1 to 4 weeks. During each iteration, a small collaborative team (typically five to ten people) conducts planning, requirements analysis, design, coding, unit testing, and acceptance testing activities with direct involvement of a customer representative. Multiple iterations are required to release a product, and larger development efforts involve several small teams working toward a common goal. The agile method is value-driven, meaning that customers set priorities at the beginning of each iteration based on perceived business value.

Agile methods emphasize face-to-face communication over written documents. Frequent communication exposes problems as they arise during the development process. Typically, a

Fig. 6.1 The Waterfall model of software development



formal meeting is held each morning during which team members report to each other what they did the previous day, what they intend to do today, and what their roadblocks are. The brief meeting, sometimes called a "stand-up," "scrum," or "huddle," usually lasts 5–15 minutes, and includes the development team, customer representatives and other stakeholders. A common implementation of agile development is Extreme Programming.

6.3.3 Software Engineering

The software development life cycle can be used to actually create the software, and understanding it is critical for those developing software in biomedical informatics. However, as the field has expanded, software has matured to the point that it is developed by and available from commercial companies, so that software development has become less of a concern for most of the field. A more important consideration in biomedical informatics has been the strategy of whether to develop and how to develop. Software vendors can spread development costs over multiple organizations, rather than one organization having to fund the full development, which can make purchasing software economically advantageous. On the other hand, as biomedical informatics remains an emerging field, the core requirements for the software continue to change, and sometimes organizations need specific capabilities that are not met by existing vendor software options. In addition to software development, informaticians often need to participate in software acquisition, and subsequent enhancements to the acquired software.

6.3.3.1 Software Acquisition

In health care information technology applications, the next significant question is whether to develop the software internally, or purchase an existing system from a vendor. As illustrated above, this "build vs. buy" is a core decision in design, and influences most of the other considerations about software.

Considerations for purchasing software begin with how the software will be selected. Software can be a component of a monolithic vendor system, be a secondary application sold by the same vendor as the EHR, or be "best-of-breed," meaning the software that meets the requirements best, independent of its architecture or source. Another consideration is whether the software needs to integrate with other applications. Some specialty applications are sufficient with minimal data sharing with other software, while other applications must be tightly integrated with existing systems to achieve a benefit. Two examples are a picture archiving and communications system (PACS) and a laboratory information system (LIS). The most important requirement for the PACS may be allowing access to images for a radiologist, who can then separately document a report. On the other hand, the LIS may need greater integration if the users require lab data to be stored in the EHR. Another consideration, related to integration, is the storage mechanism. A stand-alone system will likely have a separate database, while an integrated system may be able to store and retrieve data using a data repository. User interface deployment is also important, and possibilities include Web-based clients, **thin clients** (e.g., Citrix), and locally-installed **thick-client** applications. Functionality may be more available with a thick client, but Web-based and thin clients are easier to update and distribute to users. Finally, security and privacy considerations are critical in health care, and can influence both the requirements and design of software. Security considerations can include whether **user authentication** is shared with other applications, or what data access events are audited for identifying potential security threats.

With some notable exceptions, most health care delivery organizations today use commercial – as opposed to locally developed – EHRs. But in reality, there is a mix between building and buying. As mentioned, organizations using commercial systems still require substantial local configuration that ranges from application-specific parameter configuration to arranging multiple software applications to link together. There is no single solution, commercial or internally-developed, that meets all the health information needs of most health care organizations, and most implementations involve a mixture of software from multiple vendors. While there can be advantages to allowing best-of-breed, recently we have observed a trend among organizations to consolidate as much functionality as possible with one vendor. Another observed trend is for organizations that build systems to consider purchasing COTS, due to the substantial maintenance costs and increased functionality of the vendor solutions. Over time, organizations are expected to move from internally-developed to COTS as functionality of commercial software becomes more advanced.

Usually, if vendor software exists that meets the requirements, it is more cost-efficient to purchase the software than build it internally. This is because the vendor can spread development costs over multiple organizations, rather than one organization having to fund the full development. In fact, few organizations have the existing infrastructure and personnel to consider internal development for anything other than small applications. However, those few institutions with developed EHRs and health information systems are notable for the success of their software. So while the costs may be higher for internal development, the benefits may also be higher. Still, these institutions have invested decades in building an infrastructure that makes these benefits possible, and it is unlikely that other organizations can afford the time investment to follow the same model. Even within historically internally-developing organizations, buying systems that can integrate with the existing system is more efficient than development. An appropriate guide is therefore, "Buy where you can, build where you can't."

Once an organization decides to acquire a health information system, there are many other decisions beyond whether to build or buy. (In fact, since the costs in time and money are prohibitive for internal development, the decision to buy is typically the easiest decision to make.) The next decision is what commercial system to purchase. There is a wide variation in the functionalities between different EHR systems, even though certification efforts have defined basic functions that each system should have. Even systems with the same certified functions may approach the functions so differently that some implementations will be incongruent to an organization. The main factors an organization should consider when choosing which system are (a) the core functionality of the software, including integration with other systems, (b) total system cost, (c) the service experience of other customers, and (d) the system's certification status. Some organizations have performed systematic reviews of different commercial software offerings that can be a helpful start to identify possible vendors and understand variations between systems. For example, KLAS Research publishes periodic assessments of both software functions and vendor performance that can be used to identify potential software products. However, since systems are complex, it is important to meet with and discuss experiences with actual organizations that have used the software. This is typically done through site visits to existing customer organizations. It is also common for organizations to make a broad request of vendors for proposals to address a specific software need, especially when the needs are not standard components of EHR software.

After a commercial product is selected, an organization must then choose how extensive the software will be. EHR companies typically have a core EHR system, with additional modules that have either been developed or acquired and integrated into their system. The set of modules used by each institution varies. One organization may use the core EHR system and accompanying modules for certain specialties, such as internal medicine and family practice, while choosing to purchase separate best-of breed software for other specialties, like obstetrics/gynecology and emergency medicine, even when the core EHR vendor has functional modules for those areas. Another organization may choose to purchase and implement all specialty systems offered from the core EHR vendor, and only purchase other software if a similar module is not available from the vendor. These decisions also must be made for all ancillary systems, including laboratory, pharmacy, radiology, etc. This is both a pre-implementation decision and a long-term strategy. Once the EHR is implemented, many specialties that were not included in the initial implementation plan may request software and data integration, depending on the success of the EHR implementation.

For organizations that choose components of multiple vendor offerings to any degree, they will need to also address how to integrate the components together so that they are not disruptive to the users' workflow. There are various strategies that can be pursued to integrate modules, either at the user context (user authentication credentials are maintained), the application view (one application is viewable as a component within another application), or at the data (data are exchanged between the applications). If components are not integrated, a user must access each application separately, by opening the software application, logging into each separately, and selecting the patient within each. When data are integrated at the user context, a user moves between both applications, but the user and patient context are shared. This "single sign-on" approach alleviates one of the main barriers to the user, by facilitating the login and patient selection, while retaining all the functionality of each system. The **Clinical Context Object Workgroup** (CCOW) is a common protocol for single sign-on implementations in health care.

A deeper level of integration is at the application view. In this case, one application will have an integrated viewer to another application, that shares user and patient context, but is accessible through the user's main workflow system. The integrated viewer functions within the primary application, but acts as a portal to the data in the secondary application. With this approach, the user workflow is retained in one system, but some of the functionality in the secondary system may be reduced because the integrated viewers are not full applications.

The deepest level of integration is at the data, where actual data elements from one system are also stored in the other system. With this approach, one system is determined to be the main repository, and data from the other systems are automatically stored into the repository. This approach has the advantage of the most complete use of data, e.g., decision support logic can use data from multiple systems, which can be more accurate. The disadvantage is that the integration can be expensive, requiring new interfaces for each integrated system.

Another and often overlooked consideration of EHR software modules is the data analytics module, usually in conjunction with a data warehouse. EHR systems generally include a reporting function, where specific reports can be configured to extract data stored in the system. However, these systems often don't facilitate ad hoc reports that are commonly needed for more complicated data analysis. Additionally, if modules from multiple software vendors are used, the data reporting functions will not work unless data are fully integrated. A solution is to use a separate data warehouse and analysis system, with functions to create ad hoc reports, that can integrate data from multiple systems. Data integration with warehouses is less expensive than with repositories, because the data do not need to be synchronized. Instead, data can be extracted in batches from source systems, transformed to the warehouse data model, and then loaded into the warehouse at periodic intervals. The greatest cost of the integration is the data transformation, but this transformation is similar to what is required when receiving data through a real-time interface.

The incentives for **Meaningful Use** have important influences on the systems that are installed by an institution. As mentioned above, the ONC created a list of important EHR functions. They also created a requirement that an organization must use a "certified" system – i.e., one that has demonstrated it provides those functions – to receive the incentives, and other criteria that the functions must be used in clinical care. As a result, health care organizations are now more likely to choose among those that are certified, and are also more likely to implement functions that support the Meaningful Use measures.

6.3.3.2 Case Studies of EHR Adoption

Consider the following case studies of institutions adopting EHR systems. All examples are fictional, but reflect the reality of the issues with EHR software.

Hospital A had been using information systems for many years, dating back to when some researchers in the cardiology department built a small system to integrate data from the purchased laboratory and pharmacy information systems. Over time, the infection control group for the hospital began using the system, and contributed efforts to expand its functionality. Other departments began developing decision support rules, and the system continued to grow. Eventually, the institution made a commitment to redevelop the infrastructure to support a much larger group of users and functions, and named it A-Chart. Satisfaction with the system was high where it had been initially developed, and with other related specialties. However, over time there was disproportionate development in these areas, and clinicians in other specialties complained about the rudimentary functions, especially when compared to existing vendor systems for their specialty. As a result, the organization decided to purchase a new vendor system. This made the other specialties happy, but was a big concern to the groups that had been using A-Chart for years. These clinicians feared that they would have to reconfigure their complicated decision support rules with a new system, or worse, that functionality would no longer be supported. To alleviate concerns, representatives from each department were asked to participate in both drafting a Request for Proposals and then reviewing the proposals from four different vendors. Many clinicians liked System X, but in the end the hospital chose System Y, which seemed to have most of the same functions but was more affordable. However, System Y did not include a laboratory system, so the hospital purchased a separate laboratory system and built interfaces to connect it with the core EHR.

Integrated Delivery System (IDS) B had a different history of its EHRs. Years ago, it existed as a separate system of hospitals and clinics. Shortly after the merger of these institutions, both the hospitals and clinics purchased separate EHRs, InPatSys and CliniCare. At the time, the institution felt that each would be best off with a best-of-breed system, to support the different workflows, and there was no system that both sides of the organization could tolerate. Years later, as IDS B began to integrate care between the hospitals and clinics, the *clinicians and administrators became increasingly frustrated at how different the InPatSys and CliniCare systems were, and that they had to use two separate systems to care for the same patients. A team was formed to evaluate the options, and the CliniCare system was eventually replaced by OutPatSys, the outpatient version of InPatSys. To prevent losing data as they moved from one system to the other, the IDS IT department prepared the OutPatSys system by loading existing laboratory results and vital sign measurements from CliniCare. Then they purchased CCOW software to allow single sign-on between systems during the first 6 months of OutPatSys implementation, while they transformed the other data from CliniCare.*

Community Hospital C (CHC) had various niche information systems throughout its organization, but no EHR to organize it all together. With the availability of Meaningful Use incentives, the hospital determined it needed to finally acquire a commercial EHR. A leadership team of four people visited six different hospitals to look at how various EHRs were used. Finally, the hospital made a decision to purchase eCompuChart, because it was among the best systems and seemed best adapted to their community size. CHC hired a new chief information officer who had recently implemented eCompuChart at a community hospital in a neighboring state. They also promoted Dr. Jones, who had recently moved from another hospital that had also used eCompuChart, to chief medical information officer (CMIO). Then they contracted with DigiHealth, a consulting company with experience in implementing EHRs, to plan and coordinate the implementation with the new CMIO and CIO. Based on DigiHealth's recommendations, all existing overlapping systems were replaced with modules from eCompuChart, to simplify maintenance.

In practice, organizations rarely adopt a complete "build" or a complete "buy" strategy. EHR vendors have come a long way in the last 5–10 years in creating systems that meet the standard and even non-standard needs in health care. Still, no system exists to date that can fully address all information needs for an organization, in part because the information needs expand as more data are stored and are available. Additionally, EHR strategies become malleable over time, as commercial software capabilities increase and data become more consistent. As indicated through some of the examples above, organizational strategies may change over time to adapt to these capabilities and needs.

One consideration that is not always stated in the software selection process, but is significant in its influence over the decision, is how the organization will pay for the application. In organizations where software purchases are requested from the information technology department and budget, overall maintenance costs are considered more prominently, and software that integrates with and is a component of the overall EHR vendor offering is often selected. However, if a clinical department has direct control over their spending for the software, functionality becomes a greater concern. An additional case study illustrates this situation.

Hospital D has recently decided to purchase eCompuChart as an overall clinical information system strategy. eCompuChart has award-winning software for the emergency department and intensive care units. However, there were strong complaints about its capabilities for labor and delivery management and radiology. After considering capabilities of best-of-breed options and their ability to integrate with eCompuChart, Hospital D eventually made a split decision. The labor and delivery module for eCompuChart was purchased because *other systems with more elaborate functionality could not integrate data as well with the overall EHR. On the other hand, a separate best-of-breed system was purchased for radiology, because interfaces between the systems were seen as an acceptable solution for integrating data.*

6.3.3.3 Enhancing Acquired Software

Although most institutions will choose to acquire a system rather than building it from scratch, software engineering is still required to make the systems function effectively. This involves more than just installing and configuring the software to the local environment. There is still a significant need for software development in implementing COTS, because (1) applications must be integrated with existing systems, and (2) health care institutions increasingly develop custom applications that supplement commercial systems.

6.3.3.4 Integration with existing systems

In all but the most basic health care information technology environments, multiple software applications are used for treatment, payment, and operations purposes. A partial list of applications that might be used in a hospital environment is shown in Table 6.1.

To facilitate the sharing of information among various software applications, standards have emerged for exchanging messages and defining clinical terminology (see Chap. 7). Message exchange between different software applications enables the following scenario:

1. A patient is admitted to the hospital. A registration clerk uses the bed management system to assign the patient's location and attending physician of record.
2. The physician orders a set of routine blood tests for the patient in the inpatient EHR computerized order entry module.
3. The request for blood work is sent electronically to the laboratory information system, where the blood specimen is matched to the patient using a bar code.

Table 6.1 Partial list of software applications that may be used in a hospital setting

System	Primary users
Inpatient EHR (results review, order entry, documentation)	Physicians, nurses, allied health professionals
Pharmacy information system	Pharmacists, pharmacy technicians
Laboratory information system	Laboratory technicians, phlebotomists
Radiology information system	Radiologists, radiology technicians
Pathology information system	Pathologists
Registration/bed management	Registration staff
Hospital billing system	Medical coders
Professional services billing system	Physicians, medical coders

4. The results of the laboratory tests are sent to the results review module of the EHR

Message exchange is an effective means of integrating disparate software applications in health care when the users rely primarily on a single "workflow system" (e.g., physician uses the inpatient EHR and the laboratory technician uses the LIS). Because message exchange is handled by a sophisticated "interface engine" (see Chap. 7), little software development in the traditional sense is typically required. When a user accesses multiple workflow systems to perform a task, message exchange may not be sufficient and a deeper level of integration may be required. For example, consider the following addition to the previously described scenario:

5. The physician reviews the patient's blood work and notes that the patient may be suffering from renal insufficiency as evidenced by his elevated creatinine level.
6. The physician would like to review a trend of the patient's creatinine over the past 3 years. Because the hospital installed their commercial EHR less than a year ago, data from prior to that time are available in a legacy results review system that was developed locally. The physician logs into the legacy application (entering her username and password), searches for the correct patient, and reviews the patient's creatinine history.

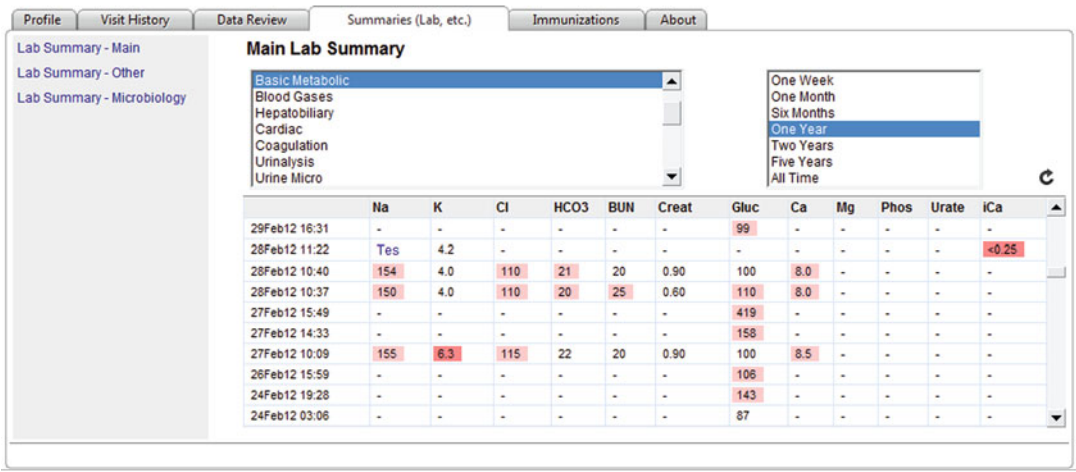


Fig. 6.2 Example screen from a custom lab summary display application integrated into a commercial EHR. The application shows a longitudinal view of laboratory results that can span multiple patient encounters

While it may seem preferable in this scenario to load all data from the legacy system into the new EHR, commercial applications may not support importing such data for various reasons. To simplify and improve the user experience for reviewing information from a legacy application within a commercial EHR, one group of informaticians created the custom application shown in Fig. 6.2. The application is accessed by clicking a link within the commercial EHR and does not require login or patient look-up.

In an example of a more sophisticated level of "workflow integration" is shown in Fig. 6.3. In this example, informaticians developed a custom billing application within an inpatient commercial EHR. Users of the application were part of a physician practice that used a different outpatient EHR with a professional billing module with which they were already familiar. When the physicians in the practice rounded on their patients who were admitted to the hospital, they documented their work by writing notes within the inpatient EHR, and then used their outpatient EHR to submit their professional service charges. This practice not only required a separate login to submit a bill, but also required duplicate patient lists to be maintained in each application, as well as a duplicate problem list for each patient to be managed in each application. The integrated charge application was accessed from the inpatient EHR but provided the same look-and-feel as the outpatient EHR billing module. Charges were submitted through the outpatient EHR infrastructure and would appear as normal charges in the outpatient system, with the substantial improvement of displaying the information (note name, author, and time) for the documentation that supported the charge.

6.3.3.5 Development of Custom Applications That Supplement or Enhance Commercial Systems

Commercial EHRs frequently provide customers with the ability to develop custom software modules. Some EHRs provide a flexible clinical decision support infrastructure that allows customers to develop modules that execute medical logic to generate alerts, reminders, corollary orders, and so on. Vendors may also provide customers with tools to access the EHR database, which allows development of stand-alone applications that make use of EHR data. Additionally, vendors may foster development of custom user interfaces within the EHR by providing an application programming interface through which developers can obtain information on user and patient context.

The ability to provide patient-specific clinical decision support is one of the key benefits of EHRs. Many commercial EHRs either directly support or have been influenced by the **Arden Syntax for Medical Logic Modules** (Pryor and

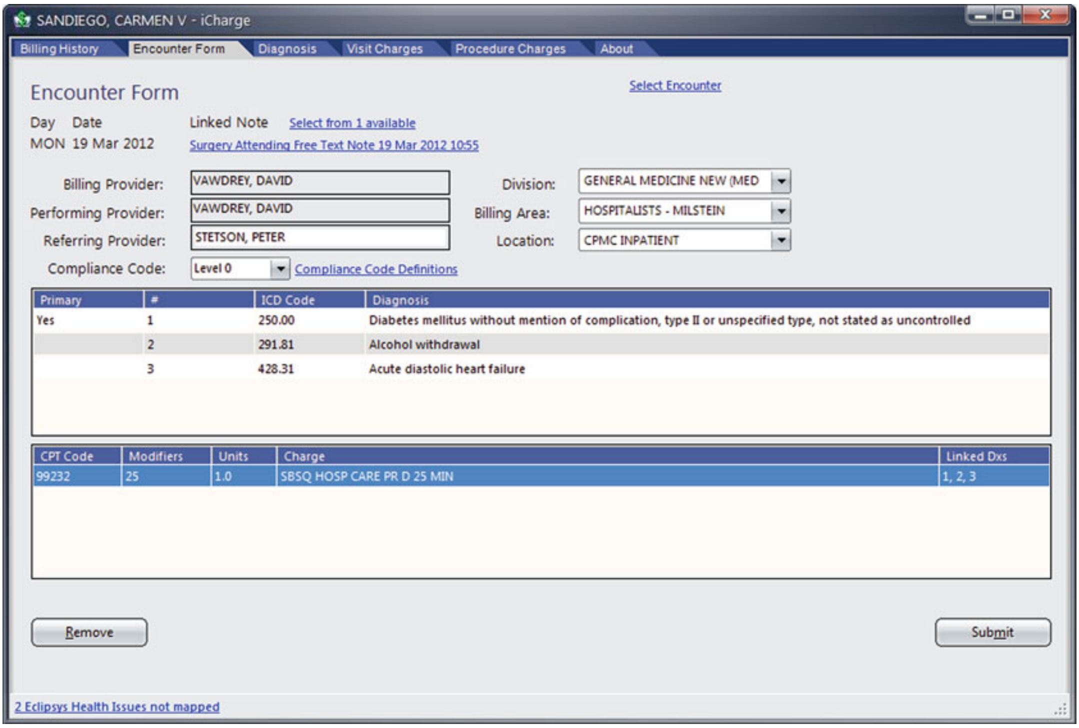


Fig. 6.3 Example screen from a custom billing application integrated into a commercial EHR. This replaced a separate application that was not integrated into the clinicians' workflow

Hripcsak 1993). The Arden Syntax is part of the **Health Level Seven** (HL7) family of standards. It encodes medical knowledge as **Medical Logic Modules** (MLMs), which can be triggered by various events within the EHR (e.g., the placing of a medication order) and execute serially as a sequence of instructions to access and manipulate data and generate output. MLMs have been used to generate clinical alerts and reminders, to screen for eligibility in clinical research studies, to perform quality assurance functions, and to provide administrative support (Dupuits 1994; Ohno-Machado et al. 1999; Jenders and Shah 2001; Jenders 2008). Although one goal of the Arden Syntax was to make knowledge portable, MLMs developed for one environment are not easily transferrable to another. Developers of clinical decision support logic require skills in both computer programming as well as medical knowledge representation.

An example of a standalone, locally developed software application that relies on EHR data is shown in Fig. 6.4. The Web-based application, EpiPortal™, provides a comprehensive, electronic hospital epidemiology decision support system. The application can be accessed from a Web browser or directly from within the EHR. It relies on EHR data such as microbiology results, clinician orders, and bed tracking information to provide users with timely information related to infection control and prevention.

In some cases, it is desirable to develop custom applications to address specific clinical needs that are not met by a commercial EHR. For example, most commercial EHRs lack dedicated tools to support patient handoff activities. For hospitalized patients, handoffs between providers affect continuity of care and increase the risk of medical errors. Informaticians at one academic medical center developed a collaborative application supporting patient handoff that is fully integrated with a commercial EHR (Fred et al. 2009). An example screen from the application is shown in

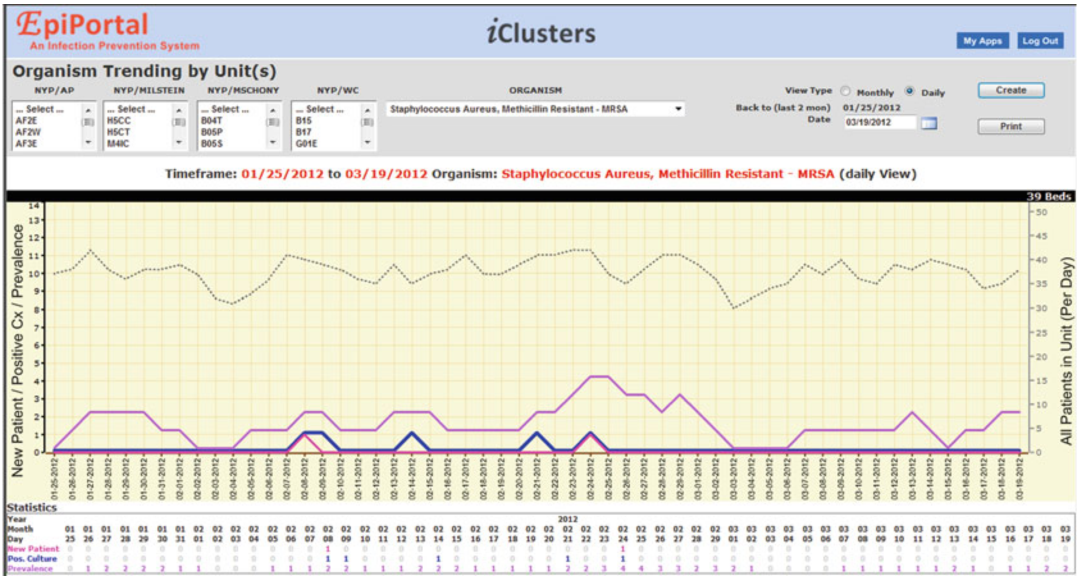


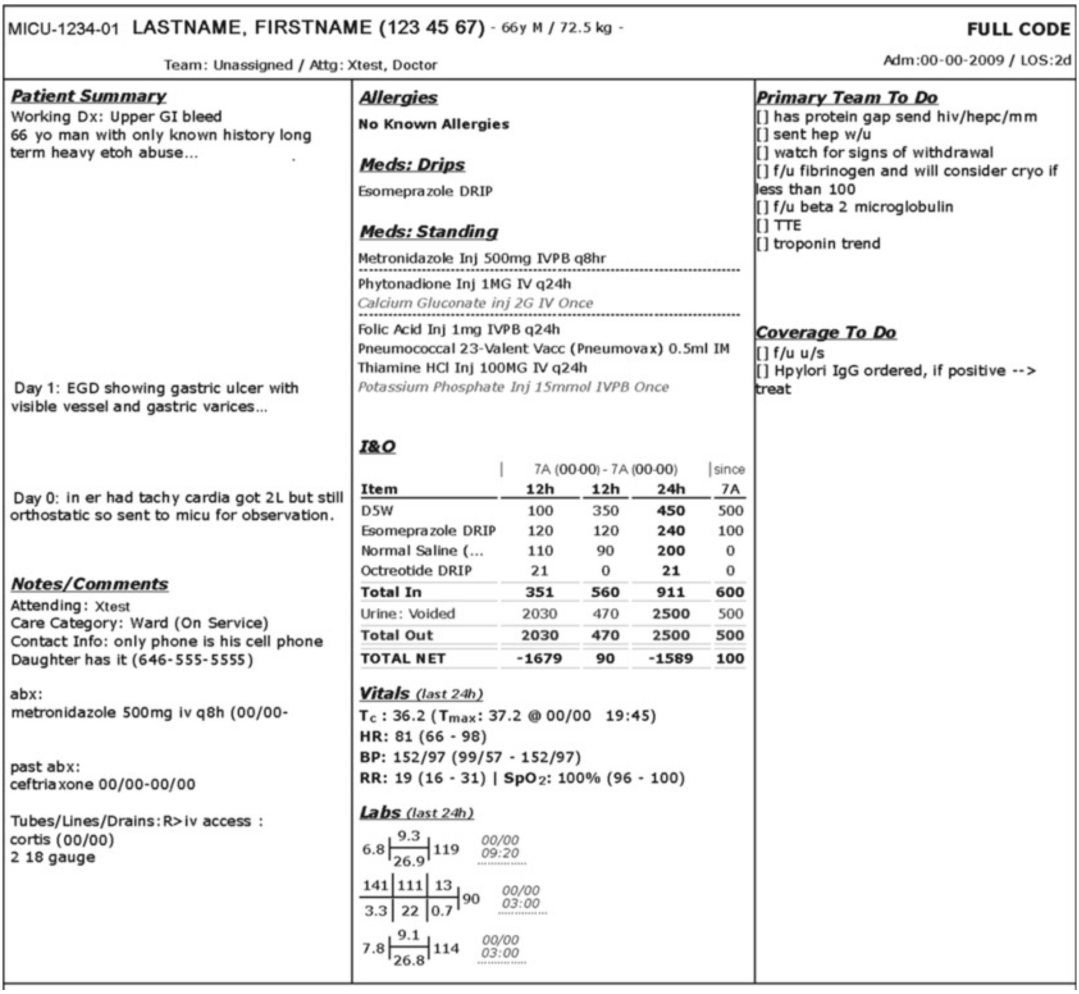
Fig. 6.4 Example screen from a standalone, software application thatrelies on EHR data to provide a comprehensive, electronic hospital epidemiology decision support system (Courtesy of New York-Presbyterian Hospital)

Fig. 6.5. The application creates user-customizable printed reports with automatic inclusion of patient allergies, active medications, 24-hour vital signs, recent common laboratory test results, isolation requirements, code status, and other EHR data. The application is currently used extensively at several academic medical centers by thousands of physicians, nurses, medical students, pharmacists, social workers, and others.

6.4 Emerging Influences and Issues

Several trends in software engineering are beginning to significantly influence biomedical information systems. While many of the trends may not be considered new to software engineering in general, they are more novel to the biomedical environment because of the less rapid and less broad adoption of information technology in this field. One area in particular that has received growing attention is **service oriented architectures** (SOA). Sometimes called “software as a service”, SOA is a software design framework that allows specific processing or information functions (services) to run on an independent computing platform that can be called by simple messages from another computer application. For example, an EHR application might have native functionality to maintain a patient’s medication list, but might call a drug-drug interaction program running on a third party system to check the patient’s medications for potential interactions. This allows the EHR provider to off-load developing this functionality, while the drug-drug interaction service provider can concentrate efforts on this focused task, and in particular on ensuring that the drug interaction database is kept up-to-date for all users of the service. Since the service is independent of any EHR application, many different EHR providers can call the same service, as can other applications such as patient health record (PHR) applications that are focused on consumer functionality. (SOA might also be grouped with the more recent computer phrase “cloud computing”, which includes providing functional services to other applications, but also encompasses running entire applications and storing data in offsite or disconnected locations.)

The important property of SOA that makes this paradigm appealing to software designers is the use of open, discoverable message formats. These message formats describe the published



MICU-1234-01 **LASTNAME, FIRSTNAME (123 45 67)** - 66y M / 72.5 kg - **FULL CODE**

Team: Unassigned / Attg: Xtest, Doctor Adm:00-00-2009 / LOS:2d

Patient Summary
Working Dx: Upper GI bleed
66 yo man with only known history long term heavy etoh abuse...

Day 1: EGD showing gastric ulcer with visible vessel and gastric varices...

Day 0: in er had tachy cardia got 2L but still orthostatic so sent to micu for observation.

Notes/Comments
Attending: Xtest
Care Category: Ward (On Service)
Contact Info: only phone is his cell phone Daughter has it (646-555-5555)

abx:
metronidazole 500mg iv q8h (00/00-

past abx:
ceftriaxone 00/00-00/00

Tubes/Lines/Drains: R>iv access :
cortis (00/00)
2 18 gauge

Allergies
No Known Allergies

Meds: Drips
Esomeprazole DRIP

Meds: Standing
Metronidazole Inj 500mg IVPB q8hr
Phytonadione Inj 1MG IV q24h
Calcium Gluconate inj 2G IV Once
Folic Acid Inj 1mg IVPB q24h
Pneumococcal 23-Valent Vacc (Pneumovax) 0.5ml IM
Thiamine HCl Inj 100MG IV q24h
Potassium Phosphate Inj 15mmol IVPB Once

I&O

	7A (00:00) - 7A (00:00)			since
Item	**12h**	**12h**	**24h**	**7A**
D5W	100	350	**450**	500
Esomeprazole DRIP	120	120	**240**	100
Normal Saline (...	110	90	**200**	0
Octreotide DRIP	21	0	**21**	0
Total In	**351**	**560**	**911**	**600**
Urine: Voided	2030	470	**2500**	500
Total Out	**2030**	**470**	**2500**	**500**
TOTAL NET	**-1679**	**90**	**-1589**	**100**

Vitals *(last 24h)*
T_c : 36.2 (T_{max}: 37.2 @ 00/00 19:45)
HR: 81 (66 - 98)
BP: 152/97 (99/57 - 152/97)
RR: 19 (16 - 31) | **SpO_2**: 100% (96 - 100)

Labs *(last 24h)*
6.8 | 9.3 / 26.9 | 119 — 00/00 09:20
141 | 111 | 13 / 3.3 | 22 | 0.7 | 90 — 00/00 03:00
7.8 | 9.1 / 26.8 | 114 — 00/00 03:00

Primary Team To Do
[] has protein gap send hiv/hepc/mm
[] sent hep w/u
[] watch for signs of withdrawal
[] f/u fibrinogen and will consider cryo if less than 100
[] f/u beta 2 microglobulin
[] TTE
[] troponin trend

Coverage To Do
[] f/u u/s
[] Hpylori IgG ordered, if positive --> treat

Fig. 6.5 Example screen from a custom patient handoff application integrated into a commercial EHR. The application creates user-customizable printed reports with automatic inclusion of patient allergies, active medications, 24-h vital signs, recent common laboratory test results, isolation requirements, code status, and other EHR data

name of the service (e.g., "Get Drug Interactions") as well as the service inputs and outputs. In the case of our drug interaction service example, the input would be the medications of interest and the output would be the interacting drugs and a description of the interaction(s). Although the services might be designed according to a proprietary **application programming interface** (API), modern implementations of SOA make use of open internet standards, particularly the **Hypertext Transfer Protocol** (HTTP), so that service providers can offer their services to a wider audience of consumers. One of the more widely used SOA protocols for the World-Wide Web is the **Simple Object Access Protocol** (SOAP), which uses HTTP and the **Extensible Markup Language** (XML) to describe the message format. SOAP also uses a simple mechanism, **Web Services Discovery Language** (WSDL), to allow service consumers to discover the format and functionality of a service. It is easy to imagine how an EHR or other biomedical application might be designed to allow use of SOA services to provide significant additional functionality, and how an application developer might allow an application user to configure a personal version of the program to call “favorite” or custom services to support specific needs.

Another important trend in clinical information systems is the development of local, regional and statewide **health information exchanges** (HIE). The HIE allows health organizations to share information about patients through a common electronic framework. The HIE is typically an independent or co-owned entity that provides the exchange service to the partner organizations. The HIE can support a query interface so that a provider can use a local EHR to search for patient data across the partner network. A subscription model can also be used to deliver relevant data as it is produced (e.g., lab results, consultation reports, etc.) to a provider on the exchange network with a need to receive that information. The HIE will often publish APIs for accessing the exchange, which could be Web-based SOA services, for example. The HIE makes it much more efficient to share patient information between organizations versus trying to create point-to-point interfaces between all the clinical information systems a particular provider might need to communicate with. Often, a large health organization will have an interface engine to link together the many disparate information systems that support clinical operations. Interfaces from the engine can be developed to support the incoming and outgoing messages from the local organization to the HIE. An important aspect of the HIE is its ability to transform or map a message from one organization’s internal format and content to a representation that can be consumed by other organizations. The HIE might require that each data provider on the exchange use standard message formats and terminologies before sending information, or the HIE might handle the data translations using a central terminology and data model mapping capability.

Software engineering is an ever-evolving discipline, and new ideas are emerging rapidly in this field. It is less than 20 years since the first graphical browser (**Mosaic**) was used to access the World Wide Web, but today Web-based applications are ubiquitous. Access to information through search engines like Google has changed the way that people find and evaluate information. Social networking applications like Facebook have altered our views on privacy and personal interaction. All of these developments have shaped the development of health care software, too. Today it is unimaginable that an EHR would not support a Web interface. Clinicians and consumers use the Web to search for health-related information in growing numbers and with growing expectations. It is not atypical for patients to discuss health issues in online forums and share intimate details on sites like PatientsLikeMe. Two other emerging developments in software engineering are also driving clinical software development: **applets** and **open source**.

Applets, or “apps”, are small programs that are designed to accomplish very focused tasks. They are also designed to run in low resource environments like smart phones and tablets. The growth of the iPhone and iPad from Apple has accelerated the growth in app development, although some may argue that it is the boom in app development by a wide variety of programmers and small software companies that has fed the growth of smart phones and other smaller computer devices. Other companies, like Google and its Android operating system, have joined in the app development frenzy. One of the appeals of apps is that they are easily available: users can find apps in “app stores” and can download them effortlessly, sometimes for free but often at very low prices. This also makes apps very democratic because many potential users can try a variety of apps with very little investment and “vote” for winners through online reviews, which encourages additional downloads by new users. In the health software environment, many apps have been developed for efficient access to medical information, such as drug indexes and anatomical viewers. Vendors are beginning to offer apps that allow views into their EHR products. EHR apps are also being written to reside entirely on mobile devices like smart phones and tablets. The question is whether the democratic nature of apps that allows users to choose the solution that best fits their personal needs fits the model of a health care organization that needs to standardize on solutions in order to share information accurately, safely and appropriately and have common training and support models. An effort by researchers at Harvard, called SMArt (Substitutable Medical Applications, reusable technologies), is seeking to build a platform and interface that allows software developers to develop medical apps that can be easily plugged together to support health care environments (Kohane and Mandl 2011).

Although the concept of open source software development, or free sharing of intellectual ideas and source code, has been around for many years, and has led to many software advances, such as **Linux** and **Apache**, its use in the medical field has been more limited. Research communities, particularly at universities, have been more supportive of open source software in support of biomedical research. But software to support medical operations has been largely dominated by commercial systems that are closed and proprietary. A notable exception is the open source version of the Veterans Affairs EHR software, VistA (Brown et al. 2003). Others have collaborated on developing open source standards for EHR components, interfaces and messaging standards. Federal efforts to push interoperability standards in health care IT are forcing vendors, independent developers, and public researchers to look to open source development. Other "special needs" areas that aren't supported widely by software vendors are also potential areas of growth for open source development.

6.5 Summary

The goal of software engineering in health care is to create a system that facilitates delivery of care. Much has changed in the past decade with EHRs, and today most institutions will purchase rather than build an EHR. But engineering these systems to facilitate care is still challenging, and following appropriate software development practices is increasingly important. The success of a system depends on interaction among designers of health care software applications and those that use the systems. Communication among the participants is very difficult when it comes to commercial applications. Informaticians have an important role to play in bridging the gaps among designers and users that result from the wide variety in background, education, experience, and styles of interaction. They can improve the process of software development by specifying accurately and realistically the need for a system and of designing workable solutions to satisfy those needs.

Suggested Readings

Carter, J. H. (2008). *Electronic health records* (2nd ed.). Philadelphia: ACP Press. Written by a clinician and for clinicians, this is a practical guide for the planning, selection, and implementation of an electronic health record. It first describes the basic infrastructure of an EHR, and then how they can be used effectively in health care. The second half of the book is written more as a workbook for someone participating in the selection and implementation of an EHR.

KLAS Reports. http://www.klasresearch.com/reports. These reports are necessary tools for a project manager who needs to know the latest industry and customer information about vendor health information technology products. The reports include information on functionality available from vendors as well as customer opinions about how vendors are meeting the needs of organizations and whose products are the best in a particular user environment.

McConnell, S. (1996). *Rapid development: Taming wild software schedules*. Redmond: Microsoft Press. For those who would like a deeper understanding of software development and project methodologies like Agile, this is an excellent source. It is targeted to code developers, system architects, and project managers.

President's Council of Advisors on Science and Technology (2010 December). Report to the President Realizing the Full Potential of Health Information Technology to Improve Healthcare for Americans: the Path Forward. http://www.whitehouse.gov/sites/default/files/microsites/ostp/pcast-health-it-report.pdf. This PCAST report focuses on what changes could be made in the field of electronic health records to make them more useful and transformational in the future. It gives a good summary of the current state of EHRs in general, and compares the barriers to those faced in adopting information technology in other fields. Time will tell if the suggestions really become the solution.

Stead, W. W., & Lin, H. S. (Eds.). (2009). *Computational technology for effective health care: Immediate steps and strategic directions*. Washington, DC: National Academies Press. This is a recent National Research Council report about the current state of health information technology and the vision of the Institute of Medicine about how such technology could be used. It can help give a good understanding of how health IT could be used in health care, especially to technology professionals without a health care background.

Tang (Chair), P. C. (2003). *Key capabilities of an electronic health record system*. Washington, DC: National Academies Press. This is a short, letter report from an Institute of Medicine committee that briefly describes the core functionalities of an electronic health record system. Much of the report is tables that list specific capabilities of EHRs in some core functional areas, and indicate their maturity in hospitals, ambulatory care, nursing homes, and personal health records.

Questions for Discussion

1. Reread the hypothetical case study in Sect. 6.2.1.
   (a) What are three primary benefits of the software used in James's care?
   (b) How many different ways is James's information used to help manage his care?
   (c) Without the software and information, how might his care be different?
   (d) How has health care that you have experienced similar or different to this example?
2. For what types of software development projects would an agile development approach be better than a waterfall approach? For what types of development would waterfall be preferred?
3. What are reasons an institution would choose to develop software instead of purchase it from a vendor?
4. How is would various stages in the software development life cycle be different when developing software versus configuring or adding enhancements to an existing software program?
5. Reread the case studies in Sect. 6.3.3.2.
   (a) What are the benefits and advantages of the different approaches to development and acquisition among the scenarios?
   (b) What were the initial costs for each institution for the software? Where will most of the long-term costs be?
6. In what ways might new trends in software (small "apps" that accomplish focused tasks) change long-term strategies for electronic health record architectures?